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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/458,019 06/01/95 JOHNSON

E A-6274-1

EXAMINER

HM31/1202  
SUGHRUE MION ZINN MACPEAK AND SEAS  
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WASHINGTON DC 20037-3202

ART UNITING H PAPER NUMBER

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/458,019</b>	Applicant(s) <b>Johnson et al</b>
	Examiner <b>Herbert J. Lilling</b>	Group Art Unit <b>1651</b>

Responsive to communication(s) filed on Oct 29, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 25-34 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 25-34 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. Receipt is acknowledged of the request for reconsideration filed October 29, 1998.

2. Claims 25-34 remain present in the instant application.

5 Claims 1-24 were previously canceled.

3. All of the prior rejections as stated in the prior Office action dated July 29, 1998 have been maintained.

10 These rejections have been restated as follows:

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15 19. The rejection as noted in the last Office action as noted in paragraph 17 has been maintained which recites:

20 Claims 25-34 **stand** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,356,810 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are within the scope of the claimed subject matter.

25 The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619

(CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

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Effective January 1, 1994, a registered attorney or agent of record may sign November 25, 1997 November 25, 1997 the assignee must fully comply with 37 CFR 3.73(b).

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It is noted that there is one inventor in common with the patent and the application, see MPEP 800-13, rev 1 Sept 1995, chart IIB--conflicting claims between APPLICATION AND A PATENT.

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The arguments submitted have been deemed not to be persuasive since the filing date is not an issue in a Double Patenting of the Obvious-type.

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According to the chart indicated above, this Examiner cannot set-up an interference to settle the conflicting claims unless there is an error in the Manual pertaining to this flow sheet.

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The arguments submitted by Applicant on April 01, 1998 have been considered but this Examiner is bound by the procedures outlined above that is in the MPEP. There is no leeway for this Examiner to change the procedure or to disregard the above action. The

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instant claims and the patented claims are not drawn to the same invention but is within the guidelines of double patenting of the obviousness type. The request that "...the only possible course of action the Examiner can pursue is to withdraw the rejection." cannot be possible but Applicant can request the Board of Appeals to overcome the rejection which is based on an impossible position placed on Applicant set-up by the MPEP chart in which one of the inventors is in common with two applications in which the applications are not commonly owned.

The arguments have been found not to be persuasive since Applicant has argued a different point and not the one as noted by the Examiner---that is, only one of the inventors and that the chart indicated the appropriate rejection.

The rejection has to be maintained based on the guidelines of the M.P.E.P. which may be in error but a higher authority must overturn the above rejection based on ~~double patenting of the obviousness type~~ as required by the MPEP chart.

20. Claims 25-34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as enabling for the claimed microorganisms in accordance with the U.S. Rules of Deposits.

It is apparent that the additional strains are required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains. See 37 C. F. R. 1.802.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed

by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

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If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

10           a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

15           b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

20           c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

25           d) a viability statement in accordance with the provisions of 37 CFR 1.807;

30           and

35           e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

35           In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

40           The prior arguments are not persuasive for one of ordinary skill in the art to reproduce all of the mutants encompassed by the claimed inventions since the claims are drawn to products and not processes.

45           Will accept product by process claims to claim all additional strains not deposited.

5 This rejection has been maintained in view of the Office requirement for deposits that are commensurate with the claimed language as noted above. The arguments have been deemed not to be persuasive to withdraw the rejections.

10 21. Claims 25-34 stand rejected under 35 U.S.C. § 112, first paragraph as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make.

15 The following decisions which may be pertinent to the claimed language which may be extremely broad for the microorganism, see:  
16 In re Fisher, 168 USPQ 18, 24 (June 11 1970)

20 Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first 25 paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

30 In view of the broad claimed language, the above statement:

35 It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art..

40 Further decision, see Fiers v. Sugano 25 USPQ2d. 1601. The decision clearly states:

45 "Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has

arrived." This above statement is complete concordance with the above decision to In re Fischer. Applicant is absolutely not entitled to the broad claimed language for the "mutant Phaffia" which "requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." Also, stated "We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility." Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains.

The arguments that the scope of the claims are enabling in view of the alleged screening methods to obtain astaxanthin mutants is not fully persuasive. As indicated above, if the claims are drawn to product by processes, the claims would be considered favorably for allowance. The scope of the claims are broader than the enabling and the rejection of the broad claimed language is in accordance with the above decision of In re Fisher Fischer and

Fiers v. Sugano..

The Claims stand rejected under 35 U.S.C. § 112, first paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same with respect to the claimed language which is considered to be extremely broad for the microorganism per se - See In re Wands 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404(fed Cir 1988) whereby it was noted the factors to be considered have been summarized as

the quantity of experimentation necessary,  
the amount of direction or guidance presented,  
the presence or absence of working examples,  
the nature of the invention,  
the state of the prior art,  
the relative skill of those in that art,  
the predictability or unpredictability of the art  
and  
the breadth of the claims

which factors in this present case presents a case of "undue experimentation" to make and practice the claimed specific microorganisms in view of the claimed language which is

considered to be extremely broad.

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness in view of the above factors and the quantity of experimentation necessary required in light of the amount of direction or guidance submitted in this instant application to isolate and practice the instant inventions without undue experimentation.

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10 22. Claims 25-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15 The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966. An adequate written description of the enzyme, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601,1606 (Fed. Cir. 1993). Accordingly, an adequate written description of a transformed microorganism requires more than a mere statement that it is part of the invention and reference to a potential method for preparing it; what is required is a description of the transformed microorganism itself.

A written description of a microorganism invention involving a genus, like a description of makeup of the claimed subject matter sufficient to distinguish it from other materials see Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284- 85 (CCPA 1973).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See

In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The lack of specificity for the broad claimed language for the products per se which are described as mutant Phaffia rhodozyma microorganisms which are capable of producing astaxanthin does not meet the description requirement which requires a precise definition of the microorganisms .

Applicant is required to be enabling for the broad scope since the record does not support the broad claimed language.

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RESPONSE TO THE REMARKS OF OCTOBER 29, 1998

The issue pertaining to the obviousness type double patenting will be reviewed and considered when Applicant overcomes all of the other rejections. This issue was discussed with the Special Program Examiner who indicated that Applicant has a possible basis that the doctrine as noted by the MPEP 800-part IIB may not apply if the subject matter of the instant application is found to be allowable based on the history of the instant application.

Absent allowable subject matter as well as a history of the prior applications, the issue of the double patenting rejection will be maintained but all favorable consideration will be given to Applicant. Especially since even if Applicant obtains broad patent coverage for the mutant strains, the prior patents would be

considered to be distinct and patentable over any claims allowed in this instant application.

The U.S. patent 5,356,810 claims subject matter which is clearly unobvious and patentable over any subject matter in the instant application. The same is true for the prior patented claims of the parent application which is clearly unobvious and patentable over any of the subject matter in the disclosure of U.S. patent 5,356,810. The instant claims can be rejected for the broadness over the prior art which is a species of the exceptionally broad claimed genus which broad claim cannot be applied against the species.

On page 12, Applicant indicates that there is a rejection under 35 U.S.C. 102(e) or 103(a) in item 21 over U.S. 5,356,810 but which is in error-rejection should be in item 21 under 35 U.S.C. 112.

There is no interference nor will one be setup pertaining to the claimed subject matter.

#### 112 rejections

Applicant has no support for the broad claimed genus and one of ordinary skill in the art would not be able to reproduce the broad claimed inventions lacking the deposits.

The claims are only enabling for the product by process which

broad claimed product by processes have been allowed.

The argued limitations are not in the instant claims which are specific type of yeast, Phaffia, and a specific recognizable mutant of that Phaffia as noted on page 5. These specific yeasts limitations are not in the claimed inventions.

The written description stands as stated-note the new rejections based on this rejection in the next paragraph(s).

The specification and claims lack the taxonomic descriptor properties which provides the property of enhanced astaxanthin production. The specification does not indicate the genes, DNA, or enzymes responsible for the specific mutants that are responsible for the enhanced production of astaxanthin. What are the specific properties, e.g. genes, DNA, or enzymes that each of the various mutants have in common.

As indicated in the above Fiers

"We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility." —

Applicant has only described the complex and unpredictable Phaffia strains by a functional utility of enhanced production of astaxanthin but lacks the definite structure in common. As well as the following: An adequate written description of the enzyme, "requires a precise definition,

such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601,1606 (Fed. Cir. 1993). Accordingly, an adequate written description of a transformed microorganism requires more than a mere statement that it is part of the invention and reference to a potential method for preparing it; what is required is a description of the transformed microorganism itself.

The lack of enablement stands in accordance with the decisions stated.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 25-34 are rejected under 35 U.S.C. 102(b/e) as anticipated by Fleno et al U.S. 5,712,110-effective filing date is April 15, 1988.

The prior art clearly anticipates the broad claimed inventions.

The instant broad claims are not supported by the instant application.

APPLICANTS HAVE CLAIMS TO MUTANTS OF PHAFFIA R. DRAWN TO STRAINS WHAT THEY DO BUT NOT WHAT THEY ARE. LACKING THIS WRITTEN DESCRIPTION AS WELL AS THE APPROPRIATE PROPERTIES ONE WOULD HAVE TO UNDERGO UNDUE EXPERIMENTAITON TO FIND ADDITIONAL STRAINS BY A SCREENING PROCESS WITHOUT ANY REASONABLE EXPECTATION OF SUCCESS.

5. Applicant is entitled to appeal the above rejections to the Patent Board of Appeals and Interference.

This Examiner will probably maintain the above rejections for the broad claimed genus especially the written description rejections with the approval of the Supervisor and the Special Program Examiner.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1651) is (703) 305-7939 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL  
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Art Unit 1651  
December 02, 1998



HERBERT J. LILLING  
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GROUP 160 ART UNIT 1651